

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

REGENERON PHARMACEUTICALS, INC.	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 1:20-cv-05502
	)	
NOVARTIS PHARMA AG, NOVARTIS	)	
TECHNOLOGY LLC, NOVARTIS	)	<b>JURY TRIAL DEMANDED</b>
PHARMACEUTICALS CORPORATION,	)	
VETTER PHARMA INTERNATIONAL	)	<b>SUBJECT TO PROTECTIVE</b>
GMBH	)	<b>ORDER; CONTAINS</b>
	)	<b>CONFIDENTIAL INFORMATION</b>
Defendant.	)	

**DEFENDANT VETTER PHARMA INTERNATIONAL GMBH'S MOTION TO  
DISMISS REGENERON'S FIRST AMENDED COMPLAINT FOR FAILURE TO  
STATE A CLAIM**

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Vetter moves to join the Motion to Dismiss For Failure to State a Claim filed by Novartis. Dkt. 89. While Counts I and II, IV, and V of Regeneron's First Amended Complaint ("FAC") are directed only to Novartis, Count III is directed to both Vetter and Novartis. Vetter joins in Novartis's Motion to Dismiss Count III rather than filing its own motion on these issues to minimize the burden on this Court. Vetter joins Novartis's Motion to Dismiss Count III for failure to state a claim for relief at least because:

- Regeneron fails to plead with plausibility or particularity that Novartis conspired with Vetter to fraudulently conceal Vetter's alleged co-ownership of the '631 Patent from Regeneron. Regeneron does not "allege enough facts to support the inference that a conspiracy actually existed." *Mayor & City Council of Baltimore, Md. v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013). Regeneron fails to offer either direct or circumstantial evidence of a "conscious commitment to a common scheme designed to achieve an unlawful objective," despite now having access to defendants' contracts. *Anderson News LLC v. Am. Media, Inc.*, 680 F.3d 162, 184 (2d Cir. 2012) (quoting *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 768 (1984)). In fact, Regeneron's nonsensical conspiracy theory ignores that Vetter specifically told Regeneron about Defendants' ownership dispute and even identified the application that later issued as the '631 patent to Regeneron. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). *See, e.g.*, Dkt. 90 ("Novartis's Brief"), 11-14.
- Regeneron still fails to plausibly allege that Novartis has monopoly—or any—power in a cognizable antitrust market. Regeneron fails to allege facts defining a plausible relevant market because it does not plead facts establishing a lack of reasonable substitutability or the absence of cross-elasticity of demand between anti-

VEGF vials and PFS products. *See Chapman v. N.Y. State Div. for Youth*, 546 F.3d 230, 237-38 (2d Cir. 2008). It further fails to allege facts establishing that Defendants have a substantial share of the purported market. *See, e.g.*, Novartis’s Brief, 16-18.

- Regeneron still fails to plausibly allege facts establishing the existence of an overarching conspiracy to limit anti-VEGF PFS products. The FAC only confirms the futility of Regeneron’s conspiracy allegations. Despite now having access to Defendants’ contracts, Regeneron does not plead any new facts showing that Novartis and Vetter agreed to demand exclusivity from any of Vetter’s customers, much less from Regeneron. Instead, the sublicense offer submitted to the Court does not include an exclusivity demand, but notably offers a *royalty-free* license. *See, e.g.*, Novartis’s Brief at 19
- Regeneron still fails to plausibly allege that Novartis harmed competition because it does not plead that Defendants foreclosed access to PFS filling services. Regeneron does not allege any facts showing that Defendants locked up “so large a percentage” of the PFS filling services market that competition was “unreasonably restricted.” *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 284 (3d Cir. 2012). *See, e.g.*, Novartis’s Brief at 20.
- Regeneron still fails to allege antitrust injury because it does not plead facts showing that it intended and was prepared to enter the purported anti-VEGF PFS market at any earlier date. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 101, 128 (1969). *See, e.g.*, Novartis’s Brief, 20-21.
- Regeneron’s claims are still untimely because it did not bring its claims within the applicable limitations period. The continuing violation doctrine does not apply because Regeneron had knowledge of its purported claims in 2013 and it does not

plead any new and independent overt acts. As pleaded, [REDACTED] is merely a reaffirmation. *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 68-69 (2d Cir. 2019). Further, the fraudulent concealment doctrine does not apply because Regeneron does not plead with particularity the extraordinary circumstances that prevented it from earlier filing claims. *Levy v. BASF Metals Limited*, 2017 WL 2533501, at \*8 (S.D.N.Y. 2017); *Smith v. McGinnis*, 208 F.3d 13, 17 (2d. Cir. 2000). *See, e.g.*, Novartis’s Brief, 21-25.

Further, Vetter incorporates by reference all of the arguments made in its Motion to Dismiss Regeneron’s Original Complaint (Dkt. 1) (“Original Complaint”), as well as its reply to that motion. Dkt. 58, 72. In addition to joining Novartis’s arguments and incorporating the arguments in Vetter’s original Motion to Dismiss by reference, Vetter submits the following additional support for dismissal of Count III against Vetter.

## **I. Background**

Rule 3.F of this Court’s Individual Practices in Civil Cases gave Regeneron the opportunity to amend its Original Complaint, and on October 21, 2020 Regeneron declined (Dkt. 59). About two weeks later, the parties completed briefing on the Defendants’ motions to dismiss, and Regeneron likely realized it had made a mistake its Original Complaint could not live with. In manufacturing a second chance, Regeneron files its FAC that, while 30 pages longer, adds nothing Regeneron could not have pleaded earlier and, more importantly, adds nothing that can save it from dismissal. If anything, Regeneron’s FAC goes so far it falls off a cliff, devolving into absurdities and contradictions as it further attempts to skirt the statute of limitations and fabricate a conspiracy between Novartis and Vetter that supposedly harmed Regeneron nearly a decade ago. It is only now, years later, that Regeneron dusts off known facts

it had no problem with at the time, to gin up antitrust claims in a transparent attempt to create leverage while it fights allegations that it willfully infringed Novartis's patent.

**A. Regeneron had the information it needed by 2014 and 2015 to argue it had an ownership interest in the '631 Patent.**

Regeneron admits in the FAC that it was aware of the application that matured into the '631 patent in 2013, *seven years* before the filing of this suit. FAC at ¶¶166, Dkt. 67-1.

Regeneron also admits in the FAC it was aware of its own work, and Vetter's work on Regeneron's behalf, that Regeneron believes gives Regeneron ownership rights in the '631 patent, *twelve years* before the filing of this suit. *See. e.g.*, FAC at ¶154. This is the only information Regeneron needed to evaluate any ownership interest in the '631 patent.

Perhaps knowing these delays doom its case, Regeneron now claims that it has learned for the first time, based on documents produced in this case in December of 2020, that Regeneron may have an ownership interest in the '631 patent. *See. e.g.*, FAC at ¶ 9. Regeneron claims, without supporting factual allegations, that it "did not and could not have discovered [REDACTED] before December 23, 2020. FAC at ¶¶178-180. The assertion that Regeneron could not have earlier known of its purported inventorship and ownership arguments for a known patent [REDACTED] is not only implausible but ludicrous.

Regeneron concedes that Vetter offered Regeneron a license to the patent application that would later issue as the '631 patent in 2013. FAC at ¶ 166. In its opposition to Vetter's motion to dismiss its Original Complaint, Regeneron attached the 2013 license proposal that Vetter sent to Regeneron. Dkt. 67-1. This document makes clear that Vetter was offering a license to intellectual property that included US application 13/750352. This application was published on January 9, 2014, as is shown on the face of the '631 patent. Regeneron had access to this public

application in February and August of 2014, when its FAC alleges negotiations with Vetter concerning the potential licenses were still ongoing. FAC at ¶¶13, 163, 179. Additionally, Regeneron had access to the '631 patent once it issued in December of 2015. The application and the eventually issued '631 patent were readily available to Regeneron. But apparently Regeneron would have this Court believe that Regeneron was so “alarmed” by Vetter’s “radical and onerous” offer of a *free* license to the '631 patent that Regeneron could not be bothered to even look at the published application or the issued patent. *Id.* at ¶¶ 166-167.

Further, Regeneron does not (and cannot) deny that [REDACTED]

Regeneron therefore possessed all the information it needed in order to determine whether it had ownership interests in the '631 patent. Regeneron’s own FAC makes this plain. For example, Regeneron alleges that by March 2008 Regeneron and Vetter developed a 1ml PFS with specific attributes. *Id.* at ¶ 154. Regeneron does not attribute this information to discovery in this litigation. Rather, Regeneron has had this since 2008 because Vetter was working on Regeneron’s behalf. Likewise, Regeneron of course had a copy of its own 2005 development agreement with Vetter that spelled out its IP rights from that collaboration.

Regeneron could have simply compared the claims of the patent application and later the '631 patent itself [REDACTED]

Access to Vetter’s development agreements with Novartis is and was unnecessary for this analysis based on Regeneron’s own admissions. *Id.* at ¶¶ 152-154.

**B. Regeneron does not plausibly plead that Vetter participated in Novartis’s decision to sue Regeneron**

Regeneron alleges that, [REDACTED]



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Regeneron's FAC asks the Court to infer that Vetter was involved in the decision to file suit against Regeneron. Indeed, Regeneron made that argument explicit in its opposition to Vetter's motion to dismiss its original complaint. Dkt. 66 at 38. However, this inference is not plausible in the context of the facts pleaded, [REDACTED]

[REDACTED]

[REDACTED] Regeneron does not plead that Vetter participated in filing the 2020 lawsuit, nor could it.

**II. The FAC does not plead facts sufficient for a "reasonable inference" that Novartis was aware of the details of the Vetter-Regeneron relationship.**

Regeneron teases in paragraph 148 of the FAC a big reveal that [REDACTED]

[REDACTED] Upon arrival, however, the big reveal is nothing more than a weak and conclusory allegation of a "reasonable inference" that Novartis knew of Regeneron's alleged intellectual property ownership rights because such contractual claims are "common in the industry." FAC at ¶¶ 161, 164. This is not enough to sustain Regeneron's complicated and contradictory narrative.

Elsewhere, Regeneron actually contradicts the very inference based on industry practice that it asks the Court to adopt. The FAC goes on, paragraph after paragraph, repeating that Regeneron was not aware of the Vetter-Novartis relationship. FAC at ¶¶ 8, 11, 15, 155. Regeneron, therefore, pleaded based on first-hand knowledge that Vetter maintains customer confidentiality. *Id.* Yet when that first-hand knowledge contradicts Regeneron's narrative, Regeneron pleads in a conclusory fashion, without any supporting factual allegations, that

Novartis *must* have known about Vetter’s relationship with Regeneron because it “was common in the industry.” *Id.* at ¶ 164. At no point does Regeneron attempt to reconcile this contradiction, much less plead facts supporting the conclusion that Vetter breached one customer’s confidentiality while respecting another’s.

### **III. The FAC’s Claims Remain Untimely as to Vetter.**

As explained in Novartis’s motion to dismiss Regeneron’s Original Complaint, the Clayton Act requires a plaintiff to sue within four years of when it feels the adverse impact of an antitrust violation. Dkt 56 at 21-23. Count III in the FAC is therefore barred by the statute of limitations against Vetter unless Regeneron can restart the statute of limitations after 2016, which requires that Vetter commit “an overt act for purposes of the continuing-violation rule.” *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 68 (2d Cir. 2019). “[A]n overt act that restarts the statute of limitations is characterized by two elements: (1) it must be a new and independent act that is not merely a reaffirmation of a previous act; and (2) it must inflict new and accumulating injury on the plaintiff.” *Id.* at 68-69 (quotation omitted).

#### **A. Regeneron’s own pursuit of follow-up discussions concerning Vetter’s 2013 license offer were not overt acts, let alone overt acts by Vetter.**

As explained Vetter’s motion to dismiss Regeneron’s Original Complaint, the only Vetter “acts” that Regeneron alleged were the 2013 license offer and Vetter’s 2017 response to Regeneron’s request to again discuss a sublicense to the ’631 Patent. Vetter’s 2017 response to Regeneron was not an overt act that tolled the statute of limitations for the reasons discussed in Vetter’s motion to dismiss Regeneron’s Original Complaint, and the reply to that motion. Dkt. 58 at 10-11, Dkt. 72 at 1-5. For example, Regeneron’s FAC still concedes that Vetter simply “reaffirm[ed] its earlier demand” in 2017. FAC at ¶ 176. Vetter’s only alleged act in 2017, then,

was a “reaffirmation of a previous act,” and therefore insufficient to restart the statute of limitations. *US Airways*, 938 F.3d at 68.

In its FAC, Regeneron pleads for the first time that negotiations concerning Vetter’s 2013 license offer to Regeneron continued into 2014. *See, e.g.*, FAC at ¶¶ 13, 163, 179. It is of no moment, as 2014 is still more than four years before this action was filed, it cannot constitute an overt act that restarts the statute of limitations. *US Airways*, 938 F.3d at 67-68.

**B. Regeneron is not entitled to equitable tolling based on the alleged fraudulent concealment.**

Equitable tolling of a statute of limitations based on fraudulent concealment requires that “(1) the defendant concealed the existence of the unlawful conduct; (2) the plaintiff remained ignorant of the violation until sometime within the statute of limitations, and (3) this continuing ignorance was not the result of a lack of diligence.” *Levy v. BASF Metals Ltd.*, 2017 WL 2533501, at \*8 (S.D.N.Y. 2017); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 249 (D. Conn. 2015). Like its other fraud claims, Regeneron must plead fraudulent concealment with particularity. *Levy*, 2017 WL 2533501, at \*8. The Second Circuit has made clear that equitable tolling should only be applied in “rare and exceptional circumstances.” *Id.*; *Smith v. McGinnis*, 208 F.3d 13, 17 (2d Cir. 2000).

Regeneron claims that Vetter agreed to “conceal its employees’ role in the inventorship of the claims in the ’631 Patent” and that therefore Regeneron could not have discovered before December of 2020 that “[REDACTED] and that Regeneron had ownership rights to those inventions.” FAC at ¶¶ 258, 274. However, as discussed above in Section I(A), Regeneron makes no allegation in its FAC that it was unaware of the work any alleged Vetter inventors did [REDACTED]—nor could it. *See, e.g.*, FAC ¶ 154.

Regeneron suggests that it needed access to development agreements between Vetter and Novartis in order to ascertain whether it had ownership rights in the '631 Patent, and/or whether any Vetter employees are inventors [REDACTED]

[REDACTED] This is nonsensical. As Regeneron knows, it had access to [REDACTED] [REDACTED] as well as the work done by both Regeneron and Vetter. Regeneron does not plead otherwise. FAC at ¶ 154. Just the opposite, Regeneron concedes that Vetter informed it of the application that would issue as the '631 Patent when it offered Regeneron a license in 2013. FAC at ¶ 166, Dkt. 67-1. Regeneron had access to the published application by January of 2014, and in any case to the claims of the '631 Patent when it issued in December 2015. December 2015 is more than four years before this action was filed, such that even if Regeneron were successful in arguing that it could not ascertain its ownership claims until then, this is still outside the period of the statute of limitations. 15 U.S.C. §15b.

Further, Regeneron acknowledges that it was aware of an “ownership” dispute between Vetter and Novartis concerning the '631 Patent, because Vetter *told Regeneron* about the dispute in 2013. Original Compl. ¶ 134, Dkt. 67-2 at 3. Regeneron had all the information it needed to determine its alleged ownership interest in the '631 Patent, and/or whether Vetter employees were inventors [REDACTED] more than four years before it filed this case. *See* Section 1(A) above.

**C. [REDACTED] was not a new overt act both because Regeneron does not plead that it inflicts a new injury, and because it does nothing but reaffirm a previous act.**

As discussed in Vetter’s reply in support of its motion to dismiss Regeneron’s Original Complaint, Regeneron did not plead that Vetter participated in Novartis’s lawsuit, or that it participated in the prosecution of the '631 Patent. Dkt. 72 at 4-5. As discussed above in section I(B), Regeneron’s FAC similarly pleads no facts that allege that Vetter participated in the

prosecution of the '631 Patent or Novartis's lawsuit, nor could it. The only allegation Regeneron's FAC does plead is that [REDACTED] is "a new and overt act" [REDACTED] FAC at ¶ 18.

As discussed above, "[a]n overt act that restarts the statute of limitations is characterized by two elements: (1) it must be a new and independent act that is not merely a reaffirmation of a previous act; and (2) it must inflict new and accumulating injury on the plaintiff." *US Airways, Inc. v. Sabre Holdings Corp.*, 938 F.3d 43, 68 (2d Cir. 2019). The FAC fails to establish either element. First, Regeneron fails to allege that [REDACTED] inflicted a *new* injury on Regeneron, or that Vetter took any specific action with respect to Regeneron as a result of [REDACTED] that harmed Regeneron. Second, [REDACTED] is not a "new and independent act." Quite the opposite, it is merely a reaffirmation. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

For at least these reasons, Regeneron should not be entitled to restart the statute of limitations, and Count III should be found untimely and dismissed with prejudice as to Vetter. *O.E.M. Glass Network, Inc. v. Mygrant Glass Co., Inc.*, 436 F. Supp. 3d 576, 582-583, 598-90 (E.D.N.Y. 2020) (dismissing one member of an alleged antitrust conspiracy when that particular defendant did not engage in an overt act more than four years prior to suit).

For these reasons, as well as those discussed in all other briefs in support of Vetter's and Novartis's motions to dismiss Regeneron's Original Complaint and FAC, the Court should dismiss Count III as untimely.

#### **IV. Conclusion**

For all of these reasons and for the reasons set out in Novartis's Brief, Vetter respectfully requests that the Court dismiss Count III.

Date: February 22, 2021

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Benjamin T. Horton, hereby certify that on February 22, 2021, I caused a copy of the foregoing **DEFENDANT VETTER PHARMA INTERNATIONAL GMBH'S MOTION TO DISMISS REGENERON'S FIRST AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM**, to be electronically filed using the CM/ECF system, which sent notification of such filing to all counsel of record.

/s/ Benjamin T. Horton

Benjamin T. Horton